

FON Research

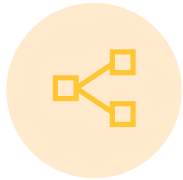
*Shahnawaz Amdani and Nadine Kasparian
Research Workgroup Co-Chairs*



Outline



Welcome!



Introducing
the group



Call for
proposals



Proposal
form



Review
criteria



Plans for
dissemination



Q&A

Please submit questions throughout the session!

Research Workgroup Members and Roles



Shahnawaz Amdani
Research Co-Chair



Jennifer Conway
PPC Co-Chair



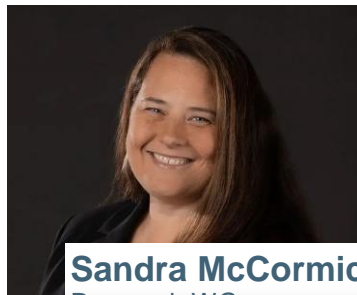
Stephen Dolgner
Research WG



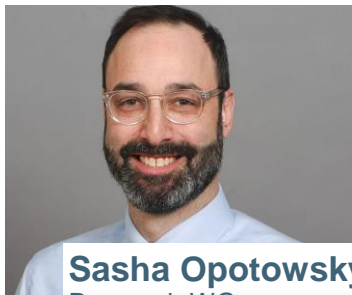
Nadine Kasparian
Research Co-Chair



David Leone
Research WG



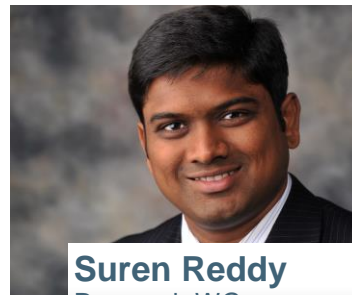
Sandra McCormick
Research WG



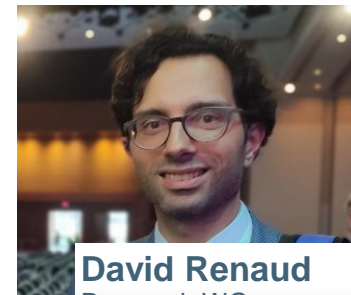
Sasha Opotowsky
Research WG



Nancy Pike
Research WG



Suren Reddy
Research WG



David Renaud
Research WG



Jack Rychik
ELT Sponsor



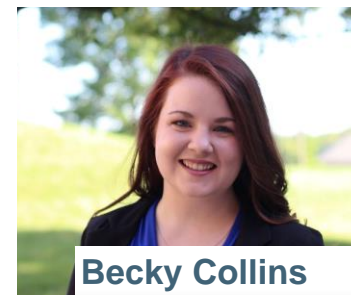
Scott Salvaggio
Research WG



Kurt Schumacher
Research WG



Sumeet Vaikunth
Research WG



Becky Collins
PM Specialist

Publications and Presentations Committee (PPC)

PCC Chair: Jennifer Conway

Committee:

Humera Ahmed

Ryan Fischer

Sunil Ghelani

Mauna Kareti

Trudy Pierick

Brandy Troisi

Adel Younoszai

Our Mission

To drive new knowledge to enhance longevity and quality of life for people of all ages with single ventricle heart disease and their families.



Call for Proposals

FON will announce our first formal call for research proposals **this summer!**



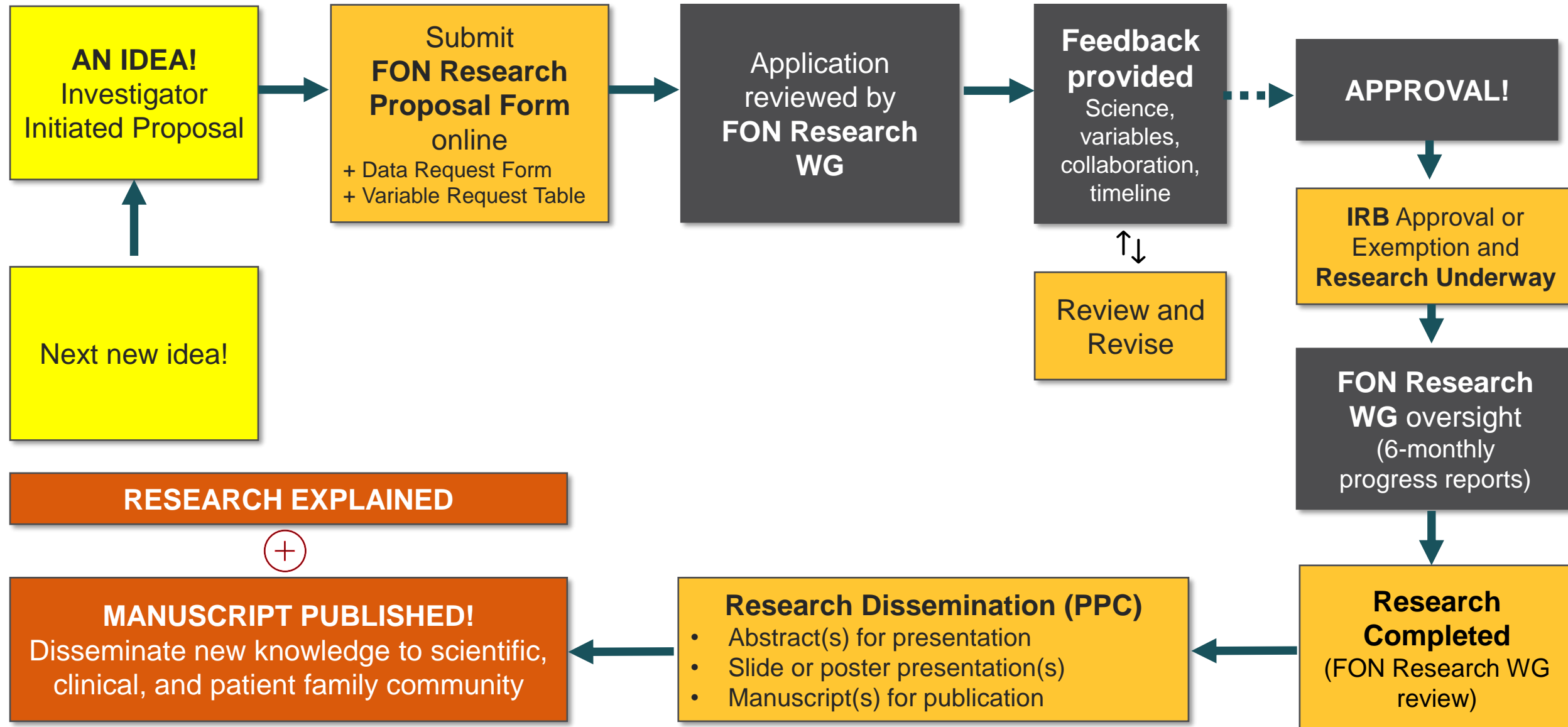
Read the newsletter and check our website for dates and more information to come.



Begin brainstorming your research project topic with your team!



Getting a FON Research Proposal from Idea to Publication



Research Proposal Form

Getting started with your submission

Research Proposal Form



I. Project Information:

Project Title:

Submission Date:

Principal Investigator:

Role of Investigator (Cardiologist, Surgeon, ICU, Nurse, APP):

Principal Investigator's Email:

Principal Investigator Institution:

Co-Investigators and Roles:

II. Checklist:

- | | | |
|---|---------------------------------------|------------------------------|
| Are you from an institution that submits data to FON: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Have you completed the Variable Request Table: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Submission type (please track all changes if a resubmission): | <input type="checkbox"/> Resubmission | <input type="checkbox"/> New |

III. Research Question, Study Aims, and Hypotheses:

The Research question should be stated as a simple question.

Research Question:

State the primary and secondary aims. Include hypotheses and outcomes for each aim (if applicable).

Primary Aim:

Secondary Aim(s):

IV. Study Design and Methods

1. **Study design:**
2. **Study sample:**
3. **Inclusion and exclusion criteria:**
4. **Primary outcome variable(s):**
5. **Secondary outcome variable(s):**
6. **Covariates and predictor variable(s):**
7. **Additional data elements required:**

V. Significance and Innovation

Indicate why this study is significant and impactful. Include prior studies, the rationale for the proposed study, and how the proposed study will improve knowledge, outcomes, practice, or patient and family experience in single ventricle heart disease. You may include brief background with references, but this section should be no longer than 250 words.

VI. Investigators and Environment

In accordance with best practices, the IRB-approved protocol, and Data Use Agreements, FON will not share any data beyond what is needed to perform the proposed analysis. If it may be unclear to those reviewing the proposal why a specific variable would be needed to perform the analysis proposed, please provide an explanation.

- 1. Prior experience with research with the FON dataset or with similar datasets:**
 No Yes, describe: _____
- 2. Name of the individual performing the statistical analysis for the project:** _____
Will their effort be paid or in-kind? If in-kind, a letter of support is required.
- 3. If this is a trainee project (student, resident, fellow), name of the primary mentor:**
 N/A Yes, _____
- 4. Is the study a single or multicenter project? If multicenter, list the collaborating centers:**
 Single center Multicenter: _____
- 5. Does the study include engagement or participation from patient, family, or community stakeholders?** No Yes, describe: _____

VII. Statistical Analysis Plan:

Consider addressing the following issues in your plan. In addition to describing what you plan to do, provide a clear explanation for why you have decided to do so and how you have considered alternative approaches.

- 1. Approach to handling missing data or outliers:**
- 2. Methods for testing statistical assumptions:**
- 3. Statistical models/tests to be used:**
- 4. For the statistical models, list the response and explanatory variables, covariates, interaction terms and other techniques used in the modeling process:**
- 5. Mockup of the anticipated tables or figures** (please attach with this form).
- 6. Sample size and power calculations:**

- ✓ **Variable Request Table** indicating exactly which variables are needed.
- ✓ **Data Request Form** indicating what format the dataset is needed in.

VIII. Study Limitations

Please provide a thoughtful, realistic perspective of the study limitations as proposed.

IX. References

X. Funding

XI. Human Subjects Research Review

Has the proposed project received approval from your institution's Institutional Review Board (IRB)?

Yes No Pending

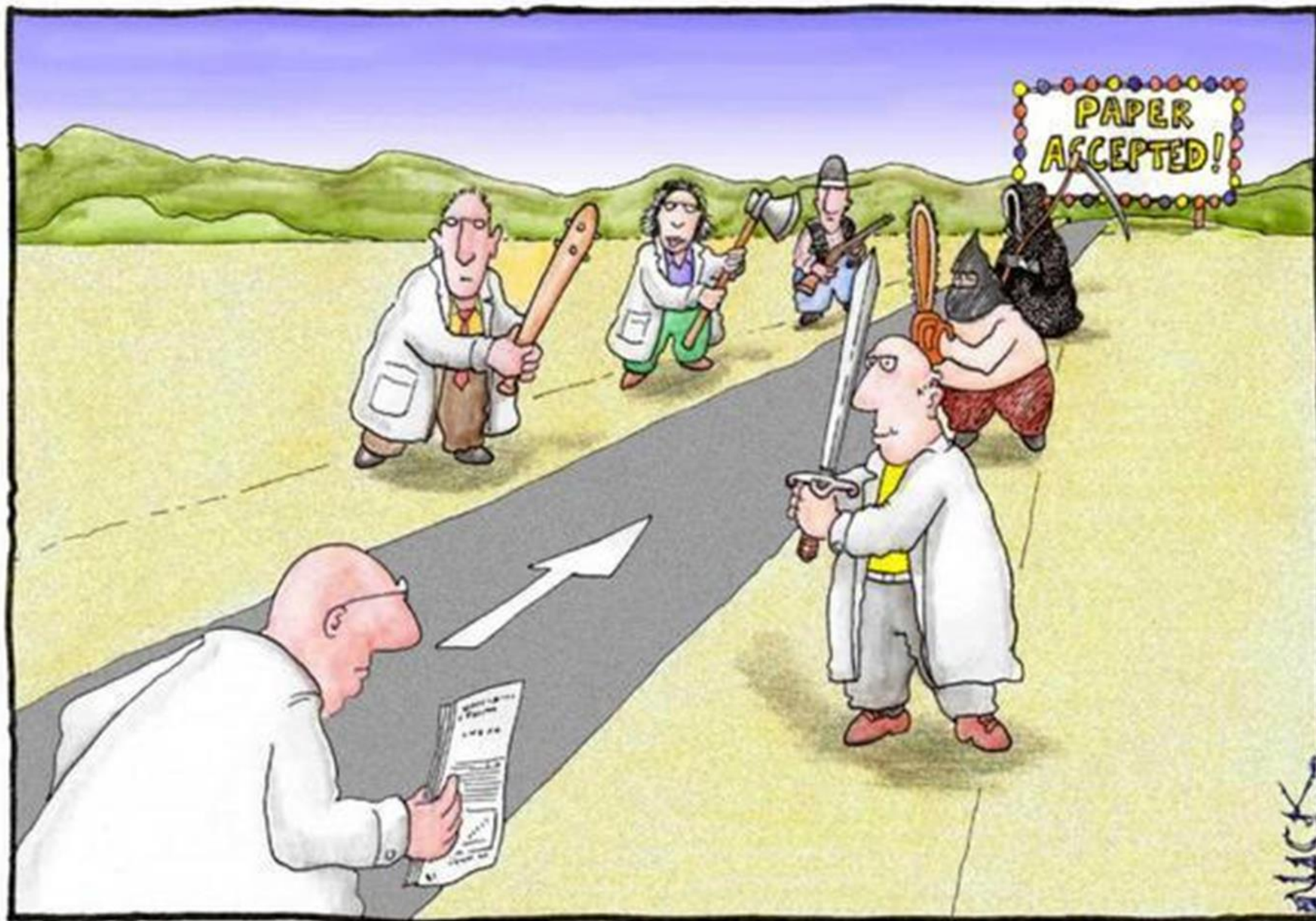
If no, why?

Note: The IRB approval letter and IRB Protocol or the IRB waiver of review must be submitted to eREG-FON@cchmc.org

XII. Other Comments

Criteria

How to address each of the four key criteria and ace your proposal!



Most scientists regarded the new streamlined peer-review process as "quite an improvement."

Area 1: Significance and Impact

Area 2: Investigators and Environment

Area 3: Approach and Methods

Area 4: Network Alignment

Area 1: Significance and Impact

- Does this project address an **important problem**, a critical barrier to progress, and/or a significant interest of the single-ventricle heart disease community?
- If the aims of the project are achieved, will scientific knowledge, technical capability, patient and family experience, clinical practice, and/or health outcomes be **improved**?
- Will successful completion of the study aims make a **meaningful impact** in the field (e.g., new idea, method, technology, preventive strategy, treatment, or service)?

Area 2: Investigators and Environment

- Is the **research team** well suited to achieve the aims of this project?
- If early career investigators are involved, do they have appropriate experience and training and a clearly defined **mentorship team**?
- If established investigators, have they demonstrated an **ongoing record of accomplishments** that have advanced their field(s)?
- If the project is collaborative or multi-PI, do the investigators have **complementary and integrated expertise**, and are their leadership approaches, governance, and organizational structures appropriate for the project?
- Do members of the research team have experience in patient and family engagement in research? **How have patient and family perspectives been incorporated?**

Area 3: Approach and Methods

- Are the proposed study methods a **good fit** for the research question?
- Are the **strategy, methodology, and proposed analyses** well-reasoned and appropriate to the aims (e.g., sufficient sample size, clear and explicit methods)?
- Does the project test new ideas, approaches, methodologies, instrumentation, or interventions which may help **develop capacity** for future research in the field?
- Does the proposal demonstrate the investigators are **competent** in the approach proposed?
- Are potential problems, **alternative strategies**, study timeline, and benchmarks presented?
- If the project involves direct patient contact or human subjects research, are the plans for (1) **protection of human subjects** from research risks, and (2) **inclusion** of minorities, members of all genders, and participants of all ages justified in terms of the scientific goals proposed?
- **Have patients and families been offered opportunities to contribute to the study design?**

Area 4: Network Alignment

- Does the proposal align with or support the **FON mission and goals**?
- Does the proposal **enhance collaboration**?
- Does the proposal involve **co-production with patients and families**?
- Has the investigator or team made a substantial **contribution to FON** (e.g., volunteer work on committees, enrollment)?

Grading System

6	Outstanding
5	Excellent
4	Good
3	Fair
2	Limited
1	Poor

- Each of the 4 review criteria are scored.
- An overall score is assigned.
- Feedback is provided on each criterion as well as the overall proposal.
- **Our Goal: To Support You!**

Research Status Report

Reporting on progress every 6 months until project completion

Progress Reports

- Provide an update on overall project status
- Any challenges or barriers to progress
- Tracking against goals and milestones
- Research outputs and achievements
- Other updates or considerations



Dissemination

Working with the PPC and Community Engagement Workgroup to share the findings of FON research



FON Expectations

- Abstracts submitted to national and international meetings.
- Poster and oral presentations.
- Manuscripts submitted for peer-review.
- Research Explained: community-friendly research summary.



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FAQs

Setting you and your team up for success

Q: *Who can apply in this first call for research proposals?*

A: This call for proposals will be for investigators from any FON member center.

Q: *In terms of research ideas, where might be a good place to start?*

A: All ideas are welcome but projects using existing FON data may be most fruitful at this stage. Investigators should tailor their request as narrowly as appropriate for their research question. Overly broad proposals are more likely to overlap with existing work and therefore may not be approvable.

Q: *Where can I find the FON Research Proposal Form?*

A: This will be available on the FON website as soon as the call opens.
www.fontanoutcomesnetwork.org

Q: Will my application need local IRB approval (or documented exempt status)?

A: Yes, in almost all cases local IRB approval (or exempt status determination) will be required before a project can start.

Q: What's an example of something that could lengthen the application process?

A: Requesting variables that are not required to complete your proposed analysis is likely to delay the review process, requiring back-and-forth for clarification, and overly broad data requests may be rejected.

Q: I would like to propose a clinical trial. Can FON serve as the Data Coordinating Center (DCC)?

A: Possibly. This will depend on the nature of the project and the scope of the request.

Q: *Does our team need to have our own statistical expert?*

A: FON does not provide statistical support at this stage. Either a statistician or another member of your team must have experience and a track record of proven competence to analyze complex data.

Q: *Can FON provide a letter of support for a grant I am submitting?*

A: Yes, but it depends on the context. FON can provide a letter of support for any project that involves collaboration between FON and an independent investigator(s). Please reach out to learn more.

Q: *Who can I reach out to if I have questions?*

A: info@fontanoutcomesnetwork.org

And please reach out to us (Shaan and Nadine), or any FON ELT member.

Next Steps

FON will formally open for research proposals this summer!



Read the newsletter and check the website for dates and more information to come!



Begin brainstorming your research project topic with your team.



Reach out to us anytime!



Discussion

Share your thoughts and questions